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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,504	10/18/2000	Marc K. Wallack	11221/5	5100

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NEW YORK, NY 10004

EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/691,504

Applicant(s)

WALLACK ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-22,29-38,55-63,70-84,86,95 and 102-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 78-96,99 and 102-107 is/are allowed.
- 6) ☒ Claim(s) 18-22,29-38,55-63,70-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response filed on 8/12/04 have been entered. Claims 18-23, 26, 29-38, 55-64, 67, 70-96, 99 and 102-107 are pending and under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in previous office actions.

Priority

Applicant's amendment to the specification to contain a specific reference to provisional application 60/240,933 in the first sentence of the specification has been entered. Priority to provisional application 60/240,933 is acknowledged. The effective priority date for this application is therefore October 18, 1999.

Claim Rejections - 35 USC § 112

The rejection of claims 18-23, 26, 29-38, 55-64, 67, 70-76 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is over claims 18-23, 26, and 29-37 in view of applicant's amendments to the claims, and **maintained over claims 38, 55-64, 67, and 70-77.**

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Applicant's amendments to the claims and arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The previous office action stated that claim 38 lacks antecedent basis for "the composition". Claim 38 depends on claim 18 which does not recite a "composition". The applicant states that claim 38 has been amended as suggested by the examiner. However, the listing of the claims provided with the 8/12/04 response does not include any amendment to claim 38. Therefore the rejection of record stands. It is suggested that applicant's amend claim 38 to recite "treated with the vaccine" instead of "treated with the composition" in order to overcome this rejection.

The previous office action stated that claim 55 contained several typographical/grammatical errors which render the claims confusing such that the metes and bounds of the claim cannot be determined. While the applicant has amended claim 55 to correct several of these errors, the following error remains. In step (b), the claim recites, "... cancer cells, **as** infected with a second....." (emphasis added). The use of the word "as" in this context is confusing such that the metes and bounds of the claim cannot be determined. It is suggested that the applicant delete the word "as" in order to overcome this rejection.

In addition, applicant's amendment to claim 55 has introduced a new error in the claim. The applicant amended claim 55, step (b) to recite, "... or are the same cancer cell type **of** the patient-derived cancer cells,..". The use of the word "of" in this context is not grammatical. It is suggested that applicant substitute the word "as" for the word "of" to overcome this rejection.

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Note that claims 56-64, 67, and 70-77 depend on claim 55 and thus have been included in this rejection.

Claims 18-23, 26, 29-38 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's amendment necessitated this new grounds of rejection. Claim 18 recites a vaccine comprising a first part and a second part. The amendment to claim 18 adds the limitation, "wherein the first recombinant vaccinia virus is administered approximately 30 minutes prior to said second part of the vaccine". Applicant's new limitation concerning administration of the vaccine renders the claim confusing as it is no longer clear whether the applicant intends to claim the vaccine product or a method of administering the vaccine product. Thus, the claims are confusing and the metes and bounds of the claim cannot be determined. Note that claims 19-23, 26, and 29-38 depend on claim 18 and thus are included in this rejection.

Claim Rejections - 35 USC § 103

The rejection of claims 18-23, 26, 29-38, 55-64, 67, 70-96, 99, and 102-107 under 35 U.S.C. 103(a) as being unpatentable over Nestle et al. (1998) Nat. Med., Vol. 4, No. 3, 328-332 in view of Sivanandham et al. (1994) J. Immunol. Immunother., Vol. 38, 259-264, is withdrawn over claims 55-64, 67, 70-96, 99, and 102-107, and **maintained over claims 18-23, 26, and 29-**

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38. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

Applicant's amendment to the claims 55-64, 67, 70-96, 99, and 102-107 to include the limitation that the first vaccinia virus is administered approximately 30 minutes prior to the composition has overcome the rejection of record for these method claims.

The applicant argues that the amendment to claims 18-23, 26, and 29-38 renders the rejection moot because the combination of Nestle and Sivandandham do not teach or suggest administering the first part of the vaccine approximately 30 minutes before the second part of the vaccine. However, unlike claims 55-64, 67, 70-96, 99, and 102-107 which are method claims, claims 18-23, 26, and 29-38 are product claims drawn to an immunotherapeutic vaccine. As such, the timing of administering the various parts of the vaccine product to a host do not carry patentable weight in the product claim. The MPEP states that, "... in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). As such, the amendment to the claims does not overcome the instant grounds of rejection.

Therefore, for the reasons of record as discussed above and in previous office actions, the rejection stands.

Claims 78-96, 99 and 102-107 are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbé', with a long horizontal flourish extending to the right.